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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Petrus Besselink

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DAYTON, OH 45402-2023

EXAMINER

HOUSTON, ELIZABETH

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,044	Applicant(s) BESSELINK, PETRUS	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/10/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 7, 11, 12, 14, 22-40, 43-47, 49, 50, 53, 54 and 60-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 13, 15-21, 41, 42, 48, 51, 52 and 55-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/21/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gianotti (US 5,836,962).

3. Gianotti discloses a medical device (1) comprising a membrane (5) and reinforcement fibers (4) coupled to said membrane to form a composite structure.

4. Claims 1-5, 13, 18-20 rejected under 35 U.S.C. 102(b) as being anticipated by Packard (US 4,646,742).

5. Packard discloses: a medical device configured to be disposed within a body lumen (10), said device comprising: a membrane (24); and reinforcement fibers (60, Fig. 2) coupled to said membrane to form a composite structure therefrom. Claim 2 and 48: further comprising a frame (12) attached to said composite structure to hold said membrane in a desired shape, said frame comprising a proximal end (for example 14) and a distal end (for example 28). Claim 3, 48, and 53: further comprising an elongated member (62,64) configured to transport said device to an appropriate location in said body lumen. Claim 4: wherein said elongated member comprises a guide wire attached (for example at 66, Fig. 4) to at least one of said frame or said composite structure.

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Claim 5: the proximal end of said frame is remote from said membrane (see Fig. 1).

Claim 13: the frame is configured to allow said guide wire to move freely in axial, radial, tangential and rotational directions within said frame when said frame is in an expanded state without influencing the position and shape of said device. Claim 18: further

comprising a hollow tube (52) advanceable into a region at least partially enclosed by said composite structure when said composite structure is in an open state (Fig. 1, 2).

Claim 19, the guide wire is configured to fit within said hollow tube (Fig. 1). Claim 20, the tube is configured (capable of) to perform at least one of a suction, flushing, inspection, measuring, clot-breaking, and retrieval device introduction functions while said tube is advanced into said at least partially enclosed region (in that the tube is capable of performing suction when the guidewire is removed).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-5, 8, 9, 13, 15, 18-21, 41, 42, 48, 51, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita (US 6,371,064) in view of Gianotti (US 5,836,962).

8. Regarding claim 1 and 48, Tsugita discloses a medical device configured to be disposed within a body lumen, said device comprising a mesh of braided fibers (25).

9. Tsugita does not disclose that the fibers are reinforcement fibers coupled to a membrane to form a composite structure. However Gianotti discloses a mesh of braided fibers similar to that of Tsugita, where each fiber is a composite structure (2) (C1:L52-53) formed from reinforcement fibers (4) coupled to a membrane (5). Gianotti discusses the advantages of using a composite fiber to increase biocompatibility without compromising necessary stiffness (C1:L29-49) as well as providing the ability to incorporate contrast medium for better positioning the device (C3:L58-62) and the ability to provide drug delivery (C4:L31-65). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate these composite fibers in place of the fibers used in the filter of Tsugita to achieve the advantages taught by Gianotti. As such, the combination would result in the fibers of Tsugita (25) becoming fibers coupled to a membrane to form the composite structure.

10. Additionally modified Tsugita discloses: Claim 2 and 48: further comprising a frame (22) attached to the fibers (mesh 25) to hold the fibers in a desired shape, said frame comprising a proximal end (111) and a distal end (112); Claim 3 and 48: further comprising an elongated member (30) configured to transport said device to an appropriate location in said body lumen; Claim 4 and 52: wherein said elongated member comprises a guide wire (30) attached to at least one of said frame or said composite structure (Fig. 4c); Claim 5: wherein said proximal end of said frame is remote from said membrane (Fig. 4c); Claim 8: further comprising a plurality of slide

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rings (111, 112), each of said slide rings connected to opposing ends of said device such that said slide rings are responsive to displacement forces imparted thereto by said guide wire; Claim 9: wherein the reinforcement fibers are directly attached to one of said slide rings and said distal end of said frame; Claim 13: wherein said frame is configured to allow said guide wire to move freely in axial, radial, tangential and rotational directions within said frame when said frame is in an expanded state without influencing the position and shape of said device (C2:L58-63); Claim 15: wherein said frame has elongated struts (181) that define attachment points at said proximal end to facilitate connection of said frame to said guide wire (Fig. 16a); Claim 18: further comprising a hollow tube (10) advance able into a region at least partially enclosed by said composite structure when said composite structure is in an open state; Claim 19: said guide wire is configured to fit within said hollow tube (C10:L40-55); Claim 20: said tube is configured to perform at least one of a suction, flushing, inspection, measuring, clot-breaking, and retrieval device introduction functions while said tube is advanced into said at least partially enclosed region (angioplasty C10:L45); Claim 21: said hollow tube is dimensioned to serve as a removal sheath for said device; Claim 41: wherein said composite structure is a filter that is expandable into an expanded state, said filter comprising a substantially closed distal end and an open proximal end such that said filter tapers from said proximal end to said distal end (Fig. 16a); Claim 42: further comprising a reservoir (defined by membrane 22) in said filter that extends from said distal end, said reservoir defining a debris storage space; Claim 51: and a plurality of stops (167, 168; C14:L53-57) affixed to said guide wire such that upon contact between

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one of said stops and one of said first or second rings due to movement of said elongated member, said device moves either into or out of said body lumen.

11. Regarding claim 55: modified Tsugita teaches first coupled to the membrane and second fibers coupled to the frame (even though all fibers would be the same, some can be chosen to be in the first group and some chosen to be in the second group) and a guidewire (30) coupled to the frame (22) and the composite structure (25) (Fig. 4c); Claim 56: the first fibers are reinforcement fibers; Claim 57: the frame is attached to the composite structure through the reinforcement fibers; Claim 58: the material making up the first and second fibers is the same; And Claim 59: the reinforcement fibers are discontinuous (since there are multiple fibers) and dispersed throughout said membrane (Fig. 3).

12. Claims 6, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita in view of Gianotti as applied to claims above, and further in view of Daniel (US 5,814,064).

13. Tsugita modified by Gianotti does not disclose that which is taught by Daniel. Daniel teaches a filter device that comprises pulling fibers (222) connecting said proximal end of said frame to said guide wire (indirectly) to enable said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body lumen (C9:L64-C10:L2). The fibers are connected to attachment points by means of attachment holes (220) disposed therein.

14. As to claim 17, Daniel teaches a fiber connected to attachment points but is silent as to how the fibers are attached. The claimed phrase "by gluing or welding" is being treated as a Product by Process limitation that is that is the fibers are attached by the process of gluing or welding. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Response to Arguments

15. Applicant's arguments filed 03/10/09 have been fully considered. Examiner has determined that part of the argument is persuasive while the other part is not. Upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of previously applied art to better clarify examiner's position. A new ground(s) of rejection is also made in view of newly found art.

16. Applicant argues that the combination of Tsugita and Gianotti does not reveal a structure where a membrane is reinforced with a fiber. Examiner previously cited Tsugita's mesh (25) as the membrane where the wires making up the membrane were

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modified by Gianotti's reinforced fiber. Examiner finds applicant's position persuasive that this combination does not result in a membrane coupled to fibers to form a composite, but rather results in a membrane made from reinforced fibers.

17. Applicant goes on to state that Gianotti shows a composite fiber which is readily distinguished from a fiber reinforcing membrane. Here, examiner respectfully disagrees. Gianotti alone, in the broadest reasonable interpretation of the term "membrane" does in fact teach a reinforcement fiber coupled to a membrane to form a composite as stated above in the 102 rejection. Thus the using Gianotti's fibers to form the filter of Tsugita as presented above in the 103 rejection does result in filter structure as claimed.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other references that would anticipate a portion of the claims include Lau (US 5,919,225); Majercak (US 2003/0225447); Broome (US 6,974,469) Kuslieka (US 2003/0171770) and Thompson (US 5,957,974).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
10/01/09